

## **REMARKS**

### **Status of the Claims**

As set forth in the Office Action Summary, Claims 1-23 are pending. Claims 15-23 stand withdrawn.

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested in light of the remarks which follow.

Applicants' representative will contact the Examiner shortly to request an interview to discuss any outstanding issues.

### **Objections**

The Amendment filed April 18, 2001 is objected to for purportedly introducing new matter into the disclosure. The Office states that although pulmonary fibrosis is encompassed by the genus of diseases, the specification does not provide disclosure to show one of skill in the art that Applicants had possession of treating the underlying cause of pulmonary fibrosis at the time of filing.

As noted in the Declaration of Diego Provvedini under 37 C.F.R. § 1.132, executed September 17, 2002, one of skill in the art would recognize that pulmonary fibrosis is included within the scope of the inflammatory and autoimmune diseases and conditions disclosed in the present specification. As noted, pulmonary fibrosis is an inflammatory disease of the lungs characterized by increased IL-1 and TNF- $\alpha$  levels, and the specification as-filed contains disclosure of disease caused by increased IL-1 and TNF- $\alpha$  levels. Further, the specification states, at page 1, that "the pathological conditions contemplated herein as benefiting from treatment with diacerein or rhein broadly encompass the inflammatory and autoimmune diseases."

Applicants request that this objection be withdrawn.

### **Response to Claim Rejections Under 35 U.S.C. § 112**

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph as being purportedly indefinite. The claims are rejected for the recitation of "underlying cause

of" as recited in claims 1 and 11, as the Office states is it unclear what underlying causes are encompassed by the claims.

Applicants refer to the paragraph which begins at the bottom of page 3 of the specification and continues to the top of page 4, stating:

[T]he administration of diacerein or rhein in the treatment of osteoarthritis derived from the unique mechanism of action of diacerein, wherein diacerein not only acted on the symptoms of the disease, inducing the short-term benefit for the patient of treating the pain and functional impairment, but in addition targeted the underlying pathologies, resulting in a long-term beneficial effect, Specifically, using the prescribed treatment protocol, it was found that diacerein had a significant effect on cartilage degradation and namely possessed activity for limiting the degradation of cartilage, and therefore for treating the course of the disease and its symptoms.

Applicants submit that one of skill in the art would understand what is meant by an underlying cause of a pathological condition, as recited in claims 1 and 11. Applicants request that this rejection be withdrawn.

### **Rejections Under 35 U.S.C. § 102**

Claims 1-14 are rejected under 35 U.S.C. 102(b) as anticipated by Great Britain No. 1,578,452 ("the 452 patent") as evidenced by U.S. Patent No. 5,986,129. Great Britain No. 1,578,452 purportedly discloses a method of treating rheumatoid arthritis and osteoarthritis using diacerhein in a dosage of 50 mg, which may be formulated as a tablet, pill or capsule. U.S. Patent No. 5,986,129 is cited as purportedly disclosing 1,8-diacylrhein.

To anticipate a claimed invention under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. See *Lindeman Maschinenfabrik GmbH v. American Hoist and Derrick Company*, 221 USPQ 481, 485

(Fed. Cir. 1984). Applicant submits that the '452 patent does not disclose each element of the present invention.

The '452 patent does not disclose a method of treating an underlying cause of a pathological condition, where the pathological condition is characterized by an increase in IL-1 and TNF- $\alpha$  levels. Further, the '452 patent does not disclose modifying the production or action of proinflammatory cytokines (including IL-1 and/or TNF $\alpha$ ) by administering diacerein or rhein.

U.S. Patent No. 5,986,129 is merely cited as evidence, as disclosing 1,8-diacyrhein, and does not itself disclose the elements of the present claims.

Applicants request that the rejection under 35 U.S.C. § 102 be withdrawn.

### **CONCLUSION**

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this paper, or the application in general, the Examiner is respectfully urged to telephone Applicants' undersigned representative so that prosecution of this application may be expedited.

Respectfully submitted,

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